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From:	Presidency
To:	Permanent Representatives Committee
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Subject:	**Unitary supplementary protection certificate proposals (Unitary SPCs)**: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013; and Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary protection certificate for plant protection products - Guidance for further work

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I. INTRODUCTION

1. On 27 April 2023, the Commission submitted four proposals concerning supplementary protection certificates for medicinal products and plant protection products. The proposals introduce the possibility of obtaining a unitary supplementary protection certificate (SPC)[1], as well as a new centralised procedure for the grant of national SPCs[2].

[1] Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 **(doc. 8869/23 + ADD 1-6)**; and proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products **(doc. 8851/23 + ADD 1-4)**.

[2] Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) (**doc. 8894/23 + ADD 1-7**); and proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) (**doc. 8887/23 + ADD 1-5**)

2. This reform of the European Union SPC framework has been announced in the Commission's 2020 Communication "Making the most of the EU's innovative potential - An intellectual property action plan to support the EU's recovery and resilience" (IP Action Plan).

3. The legislative package is aimed at achieving the following four main objectives:

   – to **reduce the current fragmentation** of the European intellectual property system resulting from divergent national practices regarding SPCs, and **to create a unitary SPC** complementing the unitary patent created by Regulation (EU) No 1257/2012 which entered into application on 1 June 2023 for 17 participating Member States;

   – to **simplify the granting of SPCs** in the Single Market and to **increase the predictability and the legal certainty** of the SPC system with a high-quality substantive examination procedure;

   – to **reduce the costs and the administrative burden** for the applicants in obtaining and maintaining SPC protection in the EU and to improve access to procedures to stakeholders, especially SMEs;

   – to **improve the monitoring of SPC protection** for all stakeholders through a single access point providing information on SPCs in the EU.

4. Regulation (EC) No 469/2009 provides for SPCs for medicinal products (both human and veterinary medicinal products), to be granted by national patent offices on the basis of national applications, on a country-by-country basis. Similarly, Regulation (EC) No 1610/96 provides for SPCs for plant protection products at national level. Together, these two measures constitute the EU's SPC regime. Currently, SPCs are only granted at the national level, and therefore only national SPCs exist. Consequently, a patent holder must file a separate application in each Member State where he wishes to obtain an SPC. Although the substantive rules are laid down by these two Regulations at EU level, the separate application procedures might lead to different outcomes. Some Member States grant an SPC for a particular product, while others refuse or grant an SPC for the same product with a different scope. This leads to legal uncertainty for rightholders and stands in stark contrast with the unitary patent system, which provides uniform protection that has equal effect in all the participating EU Member States and for which all procedural information is published centrally in the Register for unitary patent protection.

5. Under the above-mentioned four Commission proposals, SPC applications – including applications for unitary SPC protection in Member States participating in the enhanced cooperation on the unitary patent – would be examined by the European Intellectual Property Office (EUIPO) as a central authority. The EUIPO would be given the task of examining both, applications for unitary certificates and applications for certificates under a new centralised procedure to be introduced into the two existing Regulations on national SPCs. The EUIPO would also be tasked to grant unitary SPCs. This new centralised procedure would be available to all rightholders, whether they have a European patent with unitary effect or a (classical) European patent without unitary effect.

6. On 28 February 2024 the European Parliament adopted its report at first reading on the four SPC proposals.

II. WORK WITHIN THE COUNCIL

7. An initial presentation of the whole Patent Package, including the four proposals on supplementary protection certificates, was made by the Commission to the Working Party on Intellectual Property on 31 May 2023. During the month of June 2023, under the Swedish Presidency, the Working Party examined the Impact Assessment and undertook a first examination of the key elements of all four SPC proposals.

8. Under the Spanish Presidency, the Working Party completed a first full reading of the two recast proposals relating to the existing Regulations on national SPCs.

9. The Belgian Presidency built on the discussions held during the second semester of 2023 and focussed the work of the Council Working Party on the examination of the two unitary SPC proposals.

10. At its two meetings on 8 and 19 February, the Working Party concentrated on the article-by-article examination of the unitary proposals. As many of the provisions are similar in the two proposals, this examination was based mainly on the medicinal products proposal, while highlighting differences to the proposal on plant protection products as necessary. To provide delegations the opportunity to have a thorough discussion on the proposed options and to base their assessment of the proposed Regulations on the best possible understanding of the key issues at stake, at the meetings of 13 March, 12 April and 13 May, the Presidency organised a

more detailed and structured discussion, based on a questionnaire[3] with thematic blocks and a stocktaking paper[4] aimed at advancing work and seeking further guidance from delegations in view of a possible way forward.

11. A large number of delegations have provided written comments and drafting suggestions on the two unitary SPC proposals and on the two recast proposals.

III. ISSUES FOR POLITICAL GUIDANCE: INVALIDITY ACTIONS

12. The Commission proposals present a bifurcation, with, on the one hand, national courts including the Unified Patent Court (UPC) handling invalidity actions relating to national SPCs obtained via the new centralised procedure, and, on the other hand, the EUIPO and the General Court of the EU being in charge of direct invalidity actions relating to unitary SPCs.

13. **DELETED** Member States, **DELETED** have therefore expressed a strong plea for deleting the invalidity procedure before the EUIPO and for specifying that the validity of unitary SPCs should be challenged before the UPC, as the UPC is the specialised European court in the area of national SPCs based on European or unitary patents, as well as for European or unitary patents.

14. One of the reasons put forward in this context is that the suggested concept of having an invalidity procedure at the EUIPO followed by appeal procedures and actions before the General Court of the EU could cause incoherence of jurisprudence on the validity of *national* SPCs, which is subject to the exclusive jurisdiction of the UPC, and the validity of *unitary* SPCs, which is subject to the jurisdiction of the General Court.

15. Furthermore, one of the most important and frequent issues arising with regard to the validity of an SPC is the question whether the product concerned is covered by the scope of protection of the patent on which the SPC is based (*basic patent*). With the aim of ensuring high quality decisions and utmost legal certainty, the Member States participating in the enhanced cooperation on the Unitary Patent and in the UPC have conferred jurisdiction on the unitary patent to the UPC, including on the assessment of the scope of protection of the unitary patent and the interpretation of the patent claims. Those Member States therefore expressed the concern that the set up proposed by the Commission – with invalidity actions at the EUIPO

[3] WK 3025/2024
[4] doc. 9519/24

followed by appeals to the EUIPO Boards of Appeal, and ultimately actions before the General Court of the EU – would create a parallel jurisdiction on the scope of protection of the unitary patent and the interpretation of the patent claims, possibly leading to conflicting judgements and legal uncertainty.

16. The Member States participating in the UPC emphasised that the UPC provides simplified, quick, and efficient judicial procedures with high-quality decisions issued by panels comprising both legally and technically qualified judges sitting in an international composition. At the same time, the UPC has to ensure the primacy of Union law and request a preliminary ruling of the CJEU whenever necessary.

17. In response to those Member States' concerns, the Commission stated that Article 263 TFEU requires that actions against acts of bodies, offices or agencies of the Union intended to produce legal effects vis-à-vis third parties must be brought before the General Court, and that jurisdiction cannot be conferred to another court, such as the UPC, where the EUIPO is deciding on SPC applications.

18. **DELETED** Member States reiterated their request to the Commission to develop alternative solutions which would allow for the jurisdiction for invalidity actions to be attributed to the UPC. **DELETED**[5].

IV. CONCLUSIONS

19. The creation of a unitary SPC regime is an important element in supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry.

20. Significant progress has been made at Working Party level on the examination of both the recast proposals relating to national SPCs and the unitary SPC proposals, as a first reading of all four proposals (articles as well as the relevant recitals) has been completed. Further work within the Working Party on Intellectual Property is required before decisions can be taken on the main aspects of the reform, including the composition of the examination panels, the language regime for unitary SPCs and the financial aspects.

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5 **DELETED**

21. **DELETED** to confer jurisdiction over direct invalidity actions concerning unitary SPCs to the UPC if we want to avoid the risk of inefficiency, divergent jurisprudence and legal uncertainty.

22. The Presidency believes that the continuation of the discussion at Working Party level must be preceded by a political decision in principle on the fundamental configuration of the new system with regard to the dispute settlement aspects, which will have repercussions on other elements of the proposals that cannot advance without such clarity. It should be further examined which legal framework and requirements would cater for this change. Considering, hence, that this issue has an impact on other elements of the SPC proposals, guidance is sought from Coreper on how to proceed with a view to defining a possible way forward regarding the design of the system of remedies, in particular the invalidity procedure.

23. In light of the above **DELETED** Coreper is invited to:

- pronounce itself on whether it should ask the Commission to develop solutions to achieve these objectives.